DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 10 2015

Cook Medical, Inc.
Mr. David Lehr, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K133114
Trade/Device Name: Micropuncture® Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code
Dated: May 23, 2014
Received: May 27, 2014

Dear Mr. Lehr:

This letter corrects our substantially equivalent letter of July 3, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133114

Device Name
Micropuncture® Introducer Set

Indications for Use *(Describe)*
The Micropuncture Introducer Set is intended for the placement of wire guides up to .038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510(k) Summary

Micropuncture® Introducer Set Traditional 510(k)
510(k) Summary
21 CFR §807.92

Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	David Lehr, RAC
Email:	david.lehr@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 102309
Contact Fax Number:	812-332-0281
Date Prepared:	September 27, 2013 (Revised May 23, 2014)

Device Information:

Trade Name:	Micropuncture® Introducer Set
Common Name:	Introducer Set
Classification Name:	Catheter Introducer DYB (21 CFR §870.1340)

Predicate Devices:

The Micropuncture® Introducer Set is substantially equivalent to the VSI Micro-Introducer Set (Vascular Solutions, Inc., K101604) with the VSI Guidewire (K112631).

Comparison to Predicate:

It has been demonstrated that the Micropuncture® Introducer Set is comparable to the predicate device in terms of intended use, duration of use, principles of operation, technological characteristics, insertion method, and anatomical location.

Device Description:

The Micropuncture® Introducer Sets contains a coaxial catheter, a wire guide, and a needle. The device is utilized to gain access to the vasculature using the Seldinger technique.

Intended Use:

The Micropuncture Introducer Set is intended for the placement of wire guides up to .038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.

Test Data:

The proposed Micropuncture® Introducer Set was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Insertion force testing – Testing simulated percutaneous insertion force through a silicone sheet. The predetermined acceptance criteria were met.
- Coaxial catheter tensile testing – Testing verified that the hub would not be dislodged during insertion and withdrawal when utilized according to the device's intended use. The predetermined acceptance criteria were met.
- Wire guide resistance to damage testing – Testing verified that the wire guide would not show any damage or defects when subjected to repeated flexing. The predetermined acceptance criteria were met.
- Wire guide resistance to fracture testing – Testing verified that the wire guide would show no signs of fracture when subjected to the resistance to fracture testing. The predetermined acceptance criteria were met.
- Wire guide tensile strength testing – Testing verified that the distal tip of the wire guide would withstand a load of 4.0N before failure. The predetermined acceptance criterion was met.
- Wire guide torque response and torque strength testing – Testing verified that the output rotation of the wire guide would be within 90 degrees of the input rotation, and that the wire guide would withstand 10 rotations without failure. The predetermined acceptance criteria were met.
- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogen, hemocompatibility, complement activation, partial thromboplastin time, and thromboresistance) demonstrated the device as biocompatible. In conformance with the applicable sections of ISO 10993-1:2009, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and as effective as the predicate device and support a determination of substantial equivalence.